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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/186,775	11/06/98	BURGESS D	01212-0005.1

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HM22/0518

EXAMINER	
ZAGHMOUT, O	
ART UNIT	**PAPER NUMBER**
1638	13

DATE MAILED: 05/18/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/186,775	Applicant(s) Burgess et al.
	Examiner Ousama Zaghmout	Group Art Unit 1638

☒ Responsive to communication(s) filed on *Dec 13, 1999*.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-4, 6, 7, 11-18, 20, 21, and 25-37* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-4, 6, 7, 11-18, 20, 21, and 25-37* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *7*

☒ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED OFFICE ACTION

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1638.

2. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

3. Status of the claims:

Claims 1, 6, 13-14, 20, and 27 have been amended (Paper No. 9)

Claims 5, 8-10, 19, 22-24 have been canceled (Paper No. 9).

Claims 28-37 have been newly added (Paper No. 9).

Claims 1, 6, 14, 20 have been newly amended (Paper 11).

Claims 1-4, 6, 7, 11-18, 20-21, and 25-37 are pending.

Claim Rejections - 35 U.S.C. § 112

Ist Paragraph

1. The rejection of claims 1, 14 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention was withdrawn in view of the amendment of the claims.

2. Claims 1-4, 6-7, 11-18, 20-21, 25-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons of record mentioned for claims 1-27 in the previous Office action mailed 06/07/1999.

Applicants' arguments filed on 12/13/1999 (Paper No. 9) and 02/25/2000 (Paper No. 11) have been carefully considered.

A. Applicants argue in the amendment filed on 12/13/1999 (Paper No. 9) that it would be routine for one skilled in the art to make transgenic plant expressing nuclease polypeptides or polypeptide fragments as described in the specification (e.g., page 15) (paragraph 2, of the Remarks, page 11). Applicants further argue that these experiments that are needed to enable the invention would not amount to undue experimentation as defined In re Wands (paragraph 1, page 12). This is not found to be persuasive for a number of reasons: First: Applicants have not disclosed a transgenic plant that is transformed by expression constructs as claimed where inserted genes can be transcribed under any promoter. The specification teaches only a schematic diagram in Example 1 (see also Figure 1) where only a description for the use of a repressor/activator fusion protein to induce expression of barnase gene in tapetal cells is disclosed. However, no transgenic plants are produced. Second: if the inserted genes were to be driven by a tissue specific promoters, there is a likelihood that promoters in both expression

cassettes will be expressed in the same tissue at the same time where transgenic plants will not be produced. Third. If an inducible promoters were to be used, they might not be induced in the same manner and under the same conditions and as such no transgenic plants will be produced. Fourth: Those skilled in the art would recognize that not all integrated genes will be expressed to a produce a specific phenotype. The expression of a transgene does not depend only on the integration into the host genome, said transgene has to be activated which is then has to go through a number of steps such as the initiation of transcription, transcript process, transport to cytoplasm and translation of mRNA. Applicants have failed to address these enablements issue of the invention as claimed. Those skilled in the art have to test large number of constructs containing different number of bases in each one of the nucleotide sequence encoding any nuclease from any source under the transcriptional activity of any non-constitutive promoters wherein said promoters can be regulated developmentally, spatially, temporally, or chemically. Let assume for the sake of argument that the nucleotide sequence of nuclease from a single gene of any a single plant is about 1000 bases, then a person with skill in the art has to test at least 250^{250} nucleotide sequences under the transcriptional activity of one promoter in order to enable the invention if the scope of the claim was limited to one and specific nucleotide sequence. Hence, this would amount to be undue experimentation to enable the invention as claimed in this application. Moreover, the examination of relevant literature both prior and post filing has not produced any document for the Examiner with regard to regeneration of transgenic plants while utilizing a nuclease gene driven under non-

constitutively expressing promoters wherein the final product would be a viable plant as claimed. The claimed invention as currently written reads on all types of non-constitutively expressing promoters. The specification, including figure 1, does not teach those skilled in the art to practice the invention absent undue experimentation. This is what has been stated by the Examiner in previous correspondence as well as in the personal interview. The close examination of the interview summary would reveal that additional support for the invention was discussed wherein Applicants' representative agreed to furnish the Examiner with additional support for the claimed invention. The state of the art provides a tissue-specific promoter such as tapetal-specific promoter.

In view of the breadth of the claims, unpredictability, lack of guidance in the specification of the results as stated above, it is the examiner's position that one skilled in the art to which it pertains, or with which it is most nearly connected, could not practice the invention commensurate in scope with these claims without undue experimentation.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Future Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Ousama M-Faiz Zaghmout whose telephone number is (703) 308-9438. The Examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to THE MATRIX CUSTOMER SERVICE CENTER whose telephone number is (703) 308-0196.

Ousama M-Faiz Zaghmout Ph.D.

May 5, 2000

ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600